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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,767	02/06/2004	Jacob W. Mandema	021720-001310US	5592

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EXAMINER	
ZHOU, SHUBO	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
09/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,767	MANDEMA ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note that the examiner assigned to this case has changed.

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/07 has been entered.

The amendment to the claims filed 8/15/07 is acknowledged and entered.

Claims 50-77 are currently pending and under examination.

Applicants' arguments filed 8/15/07 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date, U.S. provisional application 60/511,602 filed 10/14/2003 under 35 U.S.C. 119(e) for claims 50-77. Claims 50-77 are essentially the same as cancelled claims 1-28

and are drawn to a method and a system for representing performance of a drug candidate comprising steps of receiving raw data, extracting index information, referencing information to generate a metadata file, referencing the metadata file to convert raw data into a binary file, generating a user interface comprising a menu, presenting the menu to a user, receiving a user input, causing the interface to reference and identify a subset of the binary file, and presenting the data subset. The steps of referencing information to generate a metadata file, referencing the metadata file to convert raw data into a binary file, and causing the interface to reference and identify a subset of the binary file are not supported by the provisional application 60/511,602, as set forth in the previous office action.

If applicant desires benefit of these provisional applications, applicant is invited to point to specific support by page and line number for each limitation of instant claims in the provisional application mentioned above. Priority for claims 50-77 is granted only to the filing date of the instant application filed 02/06/2004.

This is reiterated from the previous Office action mailed 11/29/06. Applicant did not address the issue in the responses filed 4/30/07 and 8/15/07, respectively.

Withdrawn Rejections/Objections

The following rejections/Objections set forth in the previous Office action are hereby withdrawn in view of applicant's amendments filed 8/15/07:

- the rejection of claims 50-77 under 35 U.S.C. 101 because the claimed invention lacks patentable utility;
- the corresponding rejection of the same claims under 35 U.S.C. 112, first

paragraph (enablement) for lacking utility;

- the rejection of claims 50-54, 62-71, 73-75, and 77 under 35 U.S.C. 103(a) as being unpatentable over Fink, U.S. Patent 5,808,918, in view of Watkins, U.S. Patent 6,457,017;

- the rejection of claims 50-51, 53-71, 73-75, and 77 under 35 U.S.C. 103(a) as being unpatentable over Herren, U.S. Patent 6,108,635, in view of Watkins, U.S. Patent 6,457,017; and

- the rejection of claims 72 and 76 under 35 U.S.C. 103(a) as being unpatentable over Herren, U.S. Patent 6,108,635, in view of Watkins, U.S. Patent 6,457,017, as applied to claims 50-51, 53-71, 73-75, and 77 above, and in view of Redlich, US 2005/0138110.

Note that the major reason for withdrawing the art rejection is that the recited references do not teach or make obvious the newly added limitation in the claims, i.e. at the interface, "the presented data subset is used for developing the model of the drug candidate's clinical safety, tolerability, and efficacy profile in relation to a competitor compound."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 50 and 75 are amended to recite at the interface, "the presented data subset is used for developing the model of the drug candidate's clinical safety, tolerability, and efficacy profile in relation to a competitor compound." While, as set forth in the previous Office action, the specification does disclose that there is a need in the art for systems for modeling the behavior of drug candidates wherein different knowledge is used for developing a model of compounds' clinical safety, tolerability, and efficacy profile in relation to the compounds' competitors, the specification does not describe an invention where in a computational system and in the context of the steps of lines 1-17, and at an interface, "the presented data subset is used for developing the model of the drug candidate's clinical safety, tolerability, and efficacy profile in relation to a competitor compound." This limitation is thus new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 recites the limitation of identifying "locations" of treatment scenario information types. It is not clear whether this means physical location (a hospital or clinic) or site of administration of a treatment (arm, leg) or some other "location". As the intended limitation is

not clear, claims 50-74 are indefinite. This rejection is reiterated from the Office action mailed 11/29/07. Applicant did not address the rejection in the response filed 8/15/07.

Claims 50 and 75 recite a binary file "relevant" to a user-selection. The metes and bounds of the "relevancy" of a binary file to a user selection are not clear. One skilled in the art would not know specific criteria for determining whether a binary file is "relevant" to a user-selection and neither claims nor the specification define establishing relationships between a user-selection and a binary file. This rejection is reiterated from the Office action mailed 11/29/07. Applicant did not address the rejection in the response filed 8/15/07.

Claim 50 in line 9 recites "the raw data file." The phrase lacks sufficient antecedent basis because there is no prior reference to a raw data file. Although raw data was recited in one of the earlier steps, "raw data" per se does not equate a "raw data file."

Claim 50 in line 18 recites "the data subset in one of a select type of presentation formats." The metes and bounds of the limitation are unclear. First, the phrase "the data subset" lacks sufficient antecedent basis. While there is prior reference to "a subset" of a binary file, there is no prior reference to "a data subset." The two phrases are different at least in scope. Second, it is not clear what is meant by "one of a select type of presentation formats." It is not clear where to present "the data subset."

Claim 50 in the penultimate line recites "developing the model of the drug candidate's clinical safety, tolerability, and efficacy profile in relation to a competitor compound." The phrase "the model" lacks sufficient antecedent basis. Whereas there is prior reference to "a model" in line 3, that model is "a model of drug candidate behavior," a generic model. The

model in the penultimate line of claim 50, however, is specifically on "the drug candidate's clinical safety, tolerability, and efficacy profile in relation to a competitor compound."

Claims 55-58 recite "the presentation format." The phrase lacks sufficient antecedent basis because there is prior reference to plural "presentation formats" in claim 50, from which claims 55-58 depend. It is thus unclear whether a particular and singular "presentation format" out of the plural "presentation formats" recited earlier is meant, and if yes, which particular one out of the multiple ones.

Claim 59 recites "the subset represents a contrast between output corresponding to two controllable variable input scenarios." It is nuclear between what is the contrast. The singular form of "output" is confusing because a contrast cannot be between a singular "output." Is "outputs" intended?

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER